

# MEDTOX®

## PROFILE®-III / PROFILE®-III A / PROFILE®-d / PROFILE®-d A / VERDICT®-III PACKAGE INSERT

The PROFILE®-III / PROFILE®-III A / PROFILE®-d / PROFILE®-d A / VERDICT®-III products are one-step qualitative screening assays for the detection of any combination of the following drugs or their metabolites in human urine: Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Methamphetamine/ 3,4 Methylendioxyamphetamine, Methadone, Opiates, Oxycodone, Phencyclidine, Propoxyphene, and THC (Cannabinoids). All PROFILE® and VERDICT® Cup products and Dip products are covered by this insert. Refer to product labeling for the drugs assayed by the kit configuration.

The adulterant strip is a one-step qualitative screening assay for the detection of Oxidants, Nitrites, and the Determination of Specific Gravity and pH Values in human urine. It is used to evaluate specimens for adulteration prior to Drugs of Abuse urine (DAU) testing. The adulterant strip is only for Forensic/Toxicology use and not for in vitro diagnostic applications.

### 1. INTENDED USE

The PROFILE®-III / PROFILE®-d / VERDICT®-III Drugs of Abuse Test is a one-step immunochromatographic test for the rapid, qualitative detection of one or more of the following: Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Methamphetamine/ 3,4 Methylendioxyamphetamine, Methadone, Opiates, Oxycodone, Phencyclidine, Propoxyphene, and THC (Cannabinoids) in human urine. It is not for over-the-counter sale. The test detects drug classes at the following cutoff concentrations:

|      |                                     |            |      |  |            |
|------|-------------------------------------|------------|------|--|------------|
| AMP  | Amphetamine (d-Amphetamine)         | 1000 ng/mL | OPI2 | Opiates (Morphine)                               | 2000 ng/mL |
| BAR  | Barbiturates (Butalbital)           | 200 ng/mL  | OPI  | Opiates (Morphine)                               | 300 ng/mL  |
| BZO  | Benzodiazepines (Nordiazepam)       | 300 ng/mL  | OXY  | Oxycodone  | 100 ng/mL  |
| COC  | Cocaine (Benzoylecgonine)           | 300 ng/mL  | PCP  | Phencyclidine (Phencyclidine)                    | 25 ng/mL   |
| MAMP | Methamphetamine (d-Methamphetamine) | 1000 ng/mL | PPX  | Propoxyphene (Norpropoxyphene)                   | 300 ng/mL  |
| MDMA | 3,4 Methylendioxyamphetamine        | 1500 ng/mL | THC  | Cannabinoids (11-nor-9-carboxy- $\Delta^9$ -THC) | 50 ng/mL   |
| MTD  | Methadone (Methadone)               | 300 ng/mL  |      |  |            |

THE PROFILE®-III / PROFILE®-d / VERDICT®-III DRUGS OF ABUSE TEST PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATE CHEMICAL METHOD MUST BE USED IN ORDER TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY/ MASS SPECTROMETRY (GC/MS) OR HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) IS THE PREFERRED CONFIRMATORY METHOD. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG OF ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE OBTAINED.

### 2. SUMMARY AND EXPLANATION OF THE TEST

Qualitative PROFILE®-III / PROFILE®-d / VERDICT®-III Drugs of Abuse Test screens utilize a one-step, solid-phase immunoassay technology to provide a very rapid test requiring no instrumentation. This test may be used to screen urine samples for one or more of the following drug classes prior to confirmatory testing:

The "Amphetamines" are a group of drugs that are central nervous system stimulants. This group includes 'amphetamine' and 'methamphetamine', and related designer drugs like '3,4 Methylendioxyamphetamine', (better known as Ecstasy or MDMA, a psychoactive drug with hallucinogenic effects).

The drug 'Amphetamine' (d-amphetamine) is detected on the device only at the (AMP) position. Both the designer drug Ecstasy (MDMA) 'Methylendioxyamphetamine' and methamphetamine (d-methamphetamine) are detected on the device at the (MAMP) position. The (MAMP) antibody does not differentiate between methamphetamine and ecstasy.

Barbiturates (BAR) are a group of structurally related prescription drugs that are used to reduce restlessness and emotional tension, induce sleep and to treat certain convulsive disorders.

Benzodiazepines (BZO), a group of structurally related central nervous system depressants, are primarily used to reduce anxiety and induce sleep.

Cocaine (COC) is a central nervous system stimulant. Its primary metabolite is benzoylecgonine.

Methadone (MTD) is a synthetic opioid used clinically as a maintenance drug for opiate abusers and for pain management.

Opiates (OPI) are a class of natural and semi-synthetic sedative narcotic drugs that include morphine, codeine and heroin.

Oxycodone (OXY) (Oxycontin®, Percodan, Percocet) is a semi synthetic narcotic analgesic that is prescribed for moderately severe pain. It is available in both standard and sustained release oral formulations. Oxycodone is metabolized to Oxymorphone and Noroxycodone.

Phencyclidine (PCP) is a hallucinogenic drug.

Propoxyphene (PPX) is a narcotic analgesic. Its primary metabolite is norpropoxyphene.

Marijuana (THC) is a hallucinogenic drug derived from the hemp plant. Marijuana contains a number of active ingredients collectively known as Cannabinoids.

Many factors influence the length of time required for drugs to be metabolized and excreted in the urine. A variety of factors influence the time period during which drug metabolites are detected in urine; the rate of urine production, the volume of fluid consumption, the amount of drug taken, the urine pH, and the length of time over which drug was consumed. Drinking large volumes of liquid or using diuretics to increase urine volume will lower the drug concentration in the urine and may decrease the detection period. Although the detection period for these drugs varies widely depending upon the compound taken, dose and route of administration and individual rates of metabolism, some general times have been established and are listed below.<sup>1-5</sup>

| <u>Drug</u>   | <u>Detection Period</u>             |
|---|-------------------------------------|
| Amphetamine<br>Acid Conditions<br>Alkaline Condition      | 1-3 days<br>3-10 days               |
| Barbiturates<br>Short-Acting<br>Long-Acting               | Up to 6 days<br>Up to 16 days       |
| Benzodiazepines   | 1-12 days                           |
| Cocaine metabolite  | Up to 5 days<br>1 to 3 days typical |
| Methadone   | 1-3 days                            |
| Methamphetamine<br>Acid Conditions<br>Alkaline Conditions | 1-3 days<br>3-10 days               |

| <u>Drug</u>                              | <u>Detection Period</u>               |
|--|---------------------------------------|
| Opiates<br>Heroin<br>Morphine<br>Codeine | 1 day<br>1-3 days<br>1-3 days         |
| Oxycodone                                | 1-3 days                              |
| PCP<br>Single Use<br>Chronic Use         | 1-8 days<br>Up to 4 weeks             |
| Propoxyphene                             | Up to 1 week                          |
| THC<br>Single Use<br>Chronic Use         | 1-7 days<br>Less than 30 days typical |

The adulterant strip is a flow strip with impregnated reagent test pads that detect specific analytes in human urine. The analytes detected are Oxidants and Nitrites. The strip also approximates the pH and specific gravity values. Urine samples with 'abnormal' values should be submitted to a reference laboratory for additional testing.

**Oxidants** The detection is based on the oxidative activity of compounds (e.g. chromate salts and/or Bleach) that catalyze the oxidation of an indicator by an organic hydroperoxide producing a blue/orange color. The color intensity is directly proportional to the concentration of Oxidants present in the sample and is observed visually and compared to the color comparator chart to obtain a result.

**Nitrites** The test is based on the principles of the Griess reaction for the detection of Nitrites. The test pad contains an amine and a coupling component. A red/orange colored azo compound is obtained by diazotization and subsequent coupling. The color intensity is directly proportional to the concentration of Nitrites present in the sample and is observed visually and compared to the color comparator chart to obtain a result.

**pH** The test paper contains indicators that change colors between pH 2 and pH 11. The color scale gives an approximate indication for pH values between those levels.

**Specific Gravity** The test pad reacts with ions in urine to indicate concentrations from 1.000 to 1.020. The color changes range from dark green with low ionic concentrations through green to yellow/orange in urines with high ionic concentrations. The color is observed visually and compared to the color comparator chart to obtain an approximate result.

### 3. PRINCIPLES OF THE PROCEDURE

The PROFILE®-III / PROFILE®-d / VERDICT®-III Drugs of Abuse Test is a one-step, competitive, membrane-based immunochromatographic assay. A single urine sample can be evaluated for the presence of each of the specified classes of drugs in a single device. The device consists of antibody-colloidal gold, drug-conjugates and a control line.

**1. ANTIBODY-COLLOIDAL GOLD** Mouse monoclonal drug antibodies were developed. Each antibody only binds drugs from the drug class tested. Antibody-colloidal gold solutions were prepared by absorbing each of the individual monoclonal antibodies to colloidal gold. The colloidal gold solutions were applied to the sample well pad in the drugs of abuse test.

**2. DRUG-CONJUGATES** Drug from the class tested was individually conjugated to bovine serum albumin (BSA) or IgG. Each drug conjugate was immobilized as a line at a labeled location on the membrane strip.

**3. CONTROL LINE** Each test strip has anti-mouse immunoglobulin antibody immobilized as a line on the membrane at the Control (C) location on the device window. The anti-mouse immunoglobulin antibody can bind to any of the mouse antibodies coated on the colloidal gold.

The device can be used to detect specific classes of drugs in urine because drug(s) in the urine and the drug(s) conjugated to the protein compete to bind to the antibody-colloidal gold in a highly specific reaction. When the test cup is tipped on its side or the dip device is dipped, urine flows into the sample pads of the device, the dried antibody-colloidal gold on the sample pad(s) dissolves and the urine wicks up the white strips carrying the reddish-purple antibody-colloidal gold as a solution with it.

#### Negative Samples

When no drug(s) is present in the urine sample, the reddish purple antibody-colloidal gold solutions migrate along the strip then binds to the appropriate drug conjugate immobilized on the membrane. The binding of the antibody-colloidal gold to the drug conjugate generates an easily visible reddish-purple line at the appropriate "T" location on the device. Strips with two tests will be labeled with two colors and are on left-hand side of device. The top color will indicate the T1 test with T1= drug test name. The bottom color will indicate the T2 test with T2= drug test name. Strips with only one color will have test results appear at the T1 position. Negative results can be reported as soon as a test line and control line are visible.

#### Non-Negative Samples

When drug(s) is present in the urine sample the antibody-colloidal gold binds to the drug(s) before it migrates along the strip. However, when the antibody-colloidal gold binds to the drug(s) in the urine, the antibody colloidal gold cannot bind to the drug conjugate immobilized on the membrane. When the drug concentration is at or above the cutoff concentration, the majority of the antibody-colloidal gold is bound to the drug from the urine. Therefore, as the drug bound antibody-colloidal gold migrates along the strip(s), it is unable to bind to the appropriate drug conjugate immobilized on the membrane. Therefore no line is generated at the drug-specific "T" location on the device for a positive sample. Read non-negative results at 5 minutes. The control line should be present for the test to be valid. The test result for Oxycodone after 5 minutes may not be consistent with the original reading. For all other tests, read results at 5 minutes or within 15 minutes of the sample application. The test result after 15 minutes may not be consistent with the original reading.

#### Control Line

Each test strip has an internal procedural control. A line must form at the Control "C" location on the device to indicate that the proper sample volume was used and that the reagents are migrating properly. If a Control line does not form, the test is considered invalid. A Control line forms when the antibody-colloidal gold binds to the anti-mouse immunoglobulin antibody immobilized on the membrane at the "C" location on the device.

#### 4. MATERIALS PROVIDED/STORAGE CONDITIONS

Each PROFILE®-III / PROFILE®-d / VERDICT®-III Drugs of Abuse Test contains all the reagents necessary to test one urine sample simultaneously for one or more drugs. Test devices are available in Cup or Dip format as described below.

##### Kit Contents – Cup Test format

Each Cup Test Kit contains twenty-five (25) test system bags and one instructional package insert or reference guide.

Each Cup Test system bag contains:

1. One (1) test device in a foil package.
  1. Each test device has test strips with drug specific reagents.
  2. The test device may contain a membrane strip laminated with adulterant pads for testing the presence of Oxidants and Nitrites, as well as determining approximate values of Specific Gravity and pH in human urine. (Products with adulterant strips only; the adulterant strip is not contained in every PROFILE®-III / PROFILE®-d / VERDICT®-III product.)
2. One (1) cup with temperature strip attached.
3. One (1) lid.
4. Two (2) lid seals.
5. One (1) Color Comparator Chart (products with adulterant strips only).

##### Kit Contents – Dip Test format

Each Dip Test Kit contains twenty-five (25) test devices in foil packages and one reference guide.

Each Dip Test device has test strips with drug specific reagents.

The test device may contain a membrane strip laminated with adulterant pads for testing the presence of Oxidants and Nitrites, as well as determining approximate values of Specific Gravity and pH in human urine. (Products with adulterant strips only; the adulterant strip is not contained in every PROFILE®-III / PROFILE®-d / VERDICT®-III product.) Adulterant strip products will contain five color comparator charts.

##### Materials Required but not provided

External controls

Timer

A urine collection container is not provided with the Dip device.

Specimen containers, external controls, disposable gloves and urine temperature strips are available from MEDTOX Diagnostics, Inc.

##### Storage Conditions

The kit, in its original packaging, should be stored at 2-25°C (36-77°F) until the expiration date on the label.

#### 5. PRECAUTIONS

1. Urine specimens and all materials coming in contact with them should be handled and disposed of as if infectious and capable of transmitting infection. Avoid contact with broken skin.
2. Avoid cross-contamination of urine samples by using a new urine specimen container for each urine sample.
3. The device should remain in its original sealed foil pouch until ready to use. If the pouch is damaged, do not use the test.
4. Do not store the test kit at temperatures above 25°C (77°F).
5. If devices have been stored refrigerated, bring to ambient temperature (18-25°C/ 64-77°F) prior to opening foil pouch.
6. Do not use tests after the expiration date printed on the package label.
7. The drug screen portion of the device is for *in vitro* diagnostic use only. The LFAS strip is for Forensic/Toxicology use only.

#### 6. SAMPLE COLLECTION AND PREPARATION

For a Cup Test, collect the urine sample in the provided cup. The urine volume should be between the minimum and maximum volume lines.

For a Dip Test, collect the urine sample in a clean specimen container.

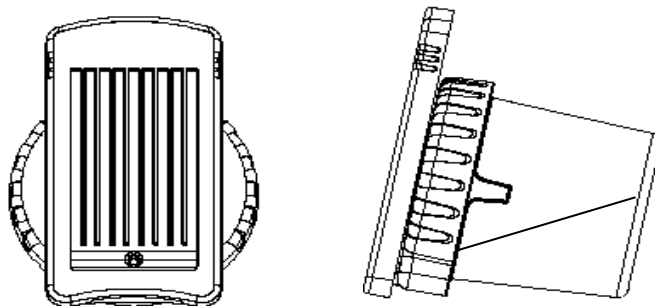
Collection of 45 mL of urine is more than sufficient for testing. No preservatives should be added. Urine may be tested immediately following collection. If it is necessary to store the urine, store under refrigeration at 2 to 8°C (36 to 46°F) for no more than two days. Urine may be frozen at -20°C (-4°F) or colder for storage. Stored urine must be brought to ambient temperature (18 to 25°C/64 to 77°F) and mixed well to assure a homogeneous sample prior to testing.

#### 7. TEST PROCEDURE

##### Cup Test

1. Bring pouched device to room temperature before opening it. Fill urine sample cup between the minimum and maximum volume lines.
2. Screw lid clock-wise onto the cup until very tight.
3. Open pouch and label the device with the patient or sample identification.
4. Connect device to lid securely as follows: Hold cup with raised sample port toward you. Hold device cassette with MEDTOX labeled end to your left. Place device cassette on top of cup lid with holes aligned. Rotate the device clockwise ¼ turn until it snaps in place.
5. Tip the cup on its side as shown below to start flow (if less than 45 ml of urine, tilt the cup forward to begin flow).
6. If adulterant strip is present, read pH, Specific Gravity, and Nitrites in vertical position as soon as color changes. Read oxidant at 60 seconds.
7. Allow the test cup to sit on its side for 5 minutes.
8. Turn the test cup upright and read the results. Control line must be present to read results. Negative results can be read as soon as a test line is visible, non-negatives at 5 minutes.

**NOTE:** Read results at 5 minutes or within 15 minutes of the sample application. Oxycodone should be read at 5 minutes. Test results interpreted after 15 minutes (for Oxycodone after 5 minutes) may not be consistent with the original results obtained at 5 minutes.



### Dip Test

1. Bring pouched device to room temperature before opening it. Obtain urine sample.
2. Open one pouch for each sample to be tested. Write patient or sample identification information on the device.
3. Pull off the clear cover to expose the fiber pads at ends of test strips.
4. Dip the cassette into the urine. The white fiber pads should be completely soaked, but do not immerse the colored part of the test strips.
5. Hold the cassette in the urine until the reddish-purple solution begins to run up all of the strips.
6. Remove the device from sample and replace the cover to protect the wet ends of the test strips.
7. If adulterant strip is present, turn device over so that the side with the adulterant strip is visible. All dip device adulterant test strip parameter pads should be wet before removing device from sample. Read adulterant strip by comparing to adulterant color comparator chart.
8. Lay cassette flat, face up for 5 minutes.
9. Read the results. Control line must be present to read results. Negative results can be read as soon as a test line is visible, non-negative at 5 minutes.

**NOTE:** Read results at 5 minutes or within 15 minutes of the sample application. Oxycodone should be read at 5 minutes. Test results interpreted after 15 minutes (for Oxycodone after 5 minutes) may not be consistent with the original results obtained at 5 minutes.

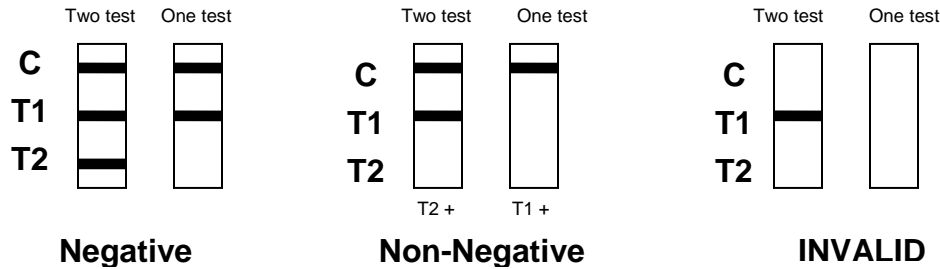
## 8. READING THE TEST RESULTS

**Negative:** The appearance of a reddish-purple line at both the control area (C) and appropriate test area (T) indicates a negative test result. **The color intensities of the control lines (C) and test lines (T) may not be equal and may vary from test to test. The test line and control line positions may vary slightly from test strip to test strip. Any line of reddish-purple color, even those of faint intensity, indicates a negative test result.**

**Non-Negative:** The appearance of a control line and the absence of a test line indicate a preliminary positive test result for that drug.

**Invalid:** The control line must be present for the test to be valid. The absence of a control line indicates the test is invalid. The urine sample should be retested on a new device.

Examples of Negative, Non-Negative and Invalid results:



There are other possible results depending on the drug or combination of drugs present in the urine sample.

## 9. INTERPRETATION OF TEST RESULTS

A **NEGATIVE** test result for a specific drug indicates that the sample does not contain the drug/drug metabolite above the cutoff level.

A **NON-NEGATIVE** test result for a specific drug indicates that the sample may contain drug/drug metabolite near or above the cutoff level. It does not indicate the level of intoxication or the specific concentration of drug in the urine sample. Non-negative samples or those with abnormal adulterant strip results should be sent to a reference laboratory for more definitive testing.

## 10. QUALITY CONTROL

An internal procedural control is included on each device. A line must form at the Control (C) position in the result window to indicate that the proper sample volume was used and that the reagents are migrating properly. If a Control line does not form, the test is considered invalid. The Control line consists of immobilized anti-mouse antibody that reacts with the antibody-colloidal gold as it passes this region of the membrane. Formation of a visible line verifies the Control line antibody antigen reaction occurred. This line may be considered an internal negative procedural control. In addition, if the test has been performed correctly and the device is working properly, the background will clear such that result lines are distinct. The cleared background may be considered an internal positive procedural control. The visible Control line (C) should always be present regardless of whether drug is absent or present in the sample.

The purpose of quality control in laboratory testing is to ensure accuracy, reliability of results and to detect errors. Because the devices are self-contained, single use tests, traditional quality control programs do not apply. The Quality Control program MEDTOX recommends for these non-instrumented test devices includes a combination of the internal device controls and external controls to ensure accuracy, reliability and to detect possible errors. The on-board reactive device controls may be one aspect of the quality program utilized by a laboratory to satisfy the daily quality control requirement established by the Laboratory Director. Another aspect of a quality control program includes an external negative control containing no drug and a positive drug control challenging to the assay cutoff concentration. These controls may be used to initially test each shipment of product received by the laboratory or to verify appropriate storage conditions and long-term stability of the test reagent. To follow good laboratory practices, we recommend that the user document the receipt of each new lot number of devices, the results of external controls performed initially and periodically thereafter, and the results of the internal controls within each device.

It is the responsibility of each Laboratory Director to demonstrate and document the validity of the alternate QC procedure they choose to use in their laboratory. For additional information or forensic and workplace testing requirements, users should contact and follow the appropriate federal, state, and local guidelines. Quality control materials are available from MEDTOX and commercial sources. Contact MEDTOX for further information.

## 11. LIMITATIONS OF THE PROCEDURE

1. The PROFILE®-III / PROFILE®-d / VERDICT®-III Drugs of Abuse Test is only for use with unadulterated human urine samples. Urine samples which are either extremely acidic (below pH 4.0) or basic (above pH 9.0) may produce erroneous results.
2. A positive result for any drug(s) does not indicate or measure intoxication. It only indicates the presence of specific drug(s) in the urine specimen.
3. Test results interpreted after 15 minutes may not be consistent with the original result obtained at 5 minutes.
4. The Drugs of Abuse Test was not evaluated in point-of-care settings.
5. There is a possibility that other substances and/or factors, e.g. technical or procedural errors, may interfere with the test and cause false results.

### Adulterant Strip limitations

The purpose of the adulterant strip is to screen for abnormal conditions in human urine samples, such as dilution or the addition of drug-test interfering substances. Occasionally medications may discolor the urine, and make it difficult to read the result. When in doubt send the urine sample to a reference laboratory for additional testing.

#### Oxidant

Nitrites, acting as oxidizing agents in solution, will produce a blue/green color change on the Oxidant pad.

#### Nitrite

Abnormal results can be caused by the presence of diagnostic or therapeutic dyes in the urine. Very high concentrations of oxidant such as 80% bleach will produce a brown color change on the Nitrite pad.

## 12. EXPECTED VALUES

The Substance Abuse and Mental Health Services Administration (SAMHSA) recommends the following screening test cutoffs:

|      |                                   |            |
|------|-----------------------------------|------------|
| AMP  | Amphetamine                       | 1000 ng/mL |
| COC  | Benzoyllecgonine                  | 300 ng/mL  |
| MAMP | Methamphetamine                   | 1000 ng/mL |
| OPI  | Morphine and Codeine              | 2000 ng/mL |
| PCP  | Phencyclidine                     | 25 ng/mL   |
| THC  | 11-nor-9-carboxy- $\Delta^9$ -THC | 50 ng/mL   |

There are no SAMHSA recommended screening levels for barbiturates, benzodiazepines, MDMA, methadone, and propoxyphene and/or their metabolites.

The Drugs of Abuse Test qualitatively detects amphetamines, barbiturates, benzodiazepines, cocaine, methamphetamine/MDMA, methadone, opiates, oxycodone, phencyclidine, propoxyphene, and THC and/or their metabolites as listed (See Specificity).

### Adulterant Strip

Urine samples that produce an abnormal result on the adulterant strip should be sent to a reference laboratory for more definitive testing to determine if the urine may be dilute, substituted, invalid and/or adulterated.

## 13. PERFORMANCE CHARACTERISTICS

### Sensitivity

The Drugs of Abuse Test detects one or more of the following drugs at cutoff levels listed below. Cutoffs for amphetamines, cocaine metabolite, methamphetamines, opiates (OPI2), phencyclidine, and cannabinoids (THC) are based on SAMHSA recommendations for screening of these drugs in human urine. The Opiate (OPI) test, if present, detects opiates below the SAMHSA recommendations for screening of opiates in human urines. There are no SAMHSA recommended screening cutoff levels for barbiturates, benzodiazepines, MDMA, methadone, Norpropoxyphene, or Propoxyphene.

|      |                                   |            |
|------|-----------------------------------|------------|
| AMP  | Amphetamine                       | 1000 ng/mL |
| BAR  | Barbiturates (Butalbital)         | 200 ng/mL  |
| BZO  | Benzodiazepines (Nordiazepine)    | 300 ng/mL  |
| COC  | Benzoyllecgonine                  | 300 ng/mL  |
| MAMP | Methamphetamine                   | 1000 ng/mL |
| MDMA | 3,4-Methylenedioxymethamphetamine | 1500 ng/mL |
| MTD  | Methadone                         | 300 ng/mL  |
| OPI2 | Morphine                          | 2000 ng/mL |
| OPI  | Morphine                          | 300 ng/mL  |
| OXY  | Oxycodone                         | 100 ng/mL  |
| PCP  | Phencyclidine                     | 25 ng/mL   |
| PPX  | Propoxyphene (Norpropoxyphene)    | 300 ng/mL  |
| THC  | 11-nor-9-carboxy- $\Delta^9$ -THC | 50 ng/mL   |

### Accuracy

A panel of naturally metabolized urine samples for the following drug(s) was analyzed using the PROFILE<sup>®</sup>-III / PROFILE<sup>®</sup>-d / VERDICT<sup>®</sup>-III Drugs of Abuse Test and the Boehringer Mannheim qualitative CEDIA<sup>®</sup> assay or the ROCHE ABUSCREEN ONLINE<sup>®</sup> for each drug and the results were compared. Results are shown in the following tables.

#### ACCURACY COMPARED TO THE BOEHRINGER MANNHEIM QUALITATIVE CEDIA<sup>®</sup> or THE ROCHE ABUSCREEN ONLINE<sup>®</sup> II ASSAYS

##### CEDIA AMPHETAMINE (1000 ng/mL cutoff)

|                         |                 | <u>Positive</u> | <u>Negative</u> | <u>TOTAL</u> |
|-------------------------|-----------------|-----------------|-----------------|--------------|
| AMP (1000 ng/mL cutoff) | Positive        | 64              | 0               | 64           |
|                         | <u>Negative</u> | <u>2</u>        | <u>618</u>      | <u>620</u>   |
|                         | TOTAL           | 66              | 618             | 684          |

Overall agreement: >99% (682/684). Samples having discrepant results were analyzed by GC/MS. The two false negative samples contained amphetamine at 2353 and 3569 ng/mL.

##### CEDIA COCAINE (300 ng/mL cutoff)

|                 |                 | <u>Positive</u> | <u>Negative</u> | <u>TOTAL</u> |
|-----------------|-----------------|-----------------|-----------------|--------------|
| COC (300 ng/mL) | Positive        | 96              | 8               | 104          |
|                 | <u>Negative</u> | <u>2</u>        | <u>578</u>      | <u>580</u>   |
|                 | TOTAL           | 98              | 586             | 684          |

Overall agreement: 99% (674/684). Samples having discrepant results were analyzed by GC/MS. Of the eight false positive samples one contained 151 ng/mL while seven did not contain cocaine metabolite detectable at the GC/MS cutoff of 150 ng/mL. The two false negative samples contained cocaine metabolite at 688 and 666 ng/mL.

ROCHE ABUSCREEN ONLINE®-II OPIATE (2000 ng/mL cutoff)

|                         |                 | <u>Positive</u> | <u>Negative</u> | <u>TOTAL</u> |
|-------------------------|-----------------|-----------------|-----------------|--------------|
| OPI (2000 ng/mL cutoff) | Positive        | 68              | 0               | 68           |
|                         | <u>Negative</u> | <u>0</u>        | <u>89</u>       | <u>89</u>    |
|                         | TOTAL           | 68              | 89              | 157          |

Overall agreement: 100% (157/157).

CEDIA OPIATE (300 ng/mL cutoff)

|                        |                 | <u>Positive</u> | <u>Negative</u> | <u>TOTAL</u> |
|------------------------|-----------------|-----------------|-----------------|--------------|
| OPI (300 ng/mL cutoff) | Positive        | 133             | 1               | 134          |
|                        | <u>Negative</u> | <u>0</u>        | <u>550</u>      | <u>550</u>   |
|                        | TOTAL           | 133             | 551             | 684          |

Overall agreement: >99% (683/684). The discrepant sample was analyzed by GC/MS. The one false positive sample did not contain morphine or codeine detectable at the GC/MS cutoff of 300 ng/mL.

CEDIA PHENCYCLIDINE (25 ng/mL cutoff)

|                |                 | <u>Positive</u> | <u>Negative</u> | <u>TOTAL</u> |
|----------------|-----------------|-----------------|-----------------|--------------|
| PCP (25 ng/mL) | Positive        | 56              | 2               | 58           |
|                | <u>Negative</u> | <u>1</u>        | <u>625</u>      | <u>626</u>   |
|                | TOTAL           | 57              | 627             | 684          |

Overall agreement: >99% (681/684). Samples having discrepant results were analyzed by GC/MS. The two false positive samples did not contain phencyclidine detectable at the GC/MS cutoff of 25ng/mL. The one false negative sample contained phencyclidine at 28 ng/mL.

CEDIA MULTI-LEVEL THC (50 ng/mL cutoff)

|                       |                 | <u>Positive</u> | <u>Negative</u> | <u>TOTAL</u> |
|-----------------------|-----------------|-----------------|-----------------|--------------|
| THC (50 ng/mL cutoff) | Positive        | 194             | 3               | 197          |
|                       | <u>Negative</u> | <u>10</u>       | <u>477</u>      | <u>487</u>   |
|                       | TOTAL           | 204             | 480             | 684          |

Overall agreement: 98% (671/684). Samples having discrepant results were analyzed by GC/MS. The three false positive samples were found to contain 16, 28, and 32 ng/mL while the ten false negative samples contained 32, 35, 41, 42, 46, 46, 49, 50, 50, and 90 ng/mL.

**RELATIVE SENSITIVITY AND SPECIFICITY COMPARED TO THE BOEHRINGER MANNHEIM QUALITATIVE CEDIA® or THE ROCHE ABUSCREEN ONLINE® II ASSAYS (Amphetamines, Cocaine, Opiates, PCP and THC)**

|      | <u>Relative Sensitivity</u> | <u>Relative Specificity</u> |
|------|-----------------------------|-----------------------------|
| AMP  | 97% (64/66)                 | 100% (618/618)              |
| COC  | 98% (96/98)                 | 99% (578/586)               |
| OPI2 | 100% (68/68)                | 100% (89/89)                |
| OPI3 | 100% (133/133)              | >99% (550/551)              |
| PCP  | 98% (56/57)                 | >99% (625/627)              |
| THC  | 95% (94/204)                | 99% (477/480)               |

**ACCURACY COMPARED to GC/MS**

|      |          | <u>PROFILE®-III / PROFILE®-d /<br/>VERDICT®-III</u> | <u>GC/MS</u> | <u>Values for discrepant<br/>Samples (ng/mL)</u> |
|------|----------|---|--------------|--|
| AMP  | Positive | 48  | 50           |  |
|      | Negative | 52  | 50           | 2353 and 3569                                    |
| COC  | Positive | 49  | 50           |  |
|      | Negative | 51  | 50           | 666  |
| OPI2 | Positive | 47  | 47           |  |
|      | Negative | 0   | 0            | No Discrepant                                    |
| OPI3 | Positive | 50  | 50           |  |
|      | Negative | 50  | 50           | No Discrepant                                    |
| PCP  | Positive | 49  | 50           |  |
|      | Negative | 51  | 50           | 28   |
| THC  | Positive | 48  | 50           |  |
|      | Negative | 52  | 50           | 35 and 46  |

**Precision (Amphetamines, Cocaine, Opiates, PCP, and THC)**

Performance around the specific cutoff for each drug was measured by testing standard drug solutions diluted in drug-free urine in replicates of 20 each on 3 different days by 3 operators. Twenty replicates of drug-free urine were also tested on each day. At 25% above the cutoff, the precision of each assay was as follows: AMP=100%, COC=100%, OPI2= 96.7%, OPI= 100%, PCP=100% and THC= 95%.

**Reproducibility (Amphetamines, Cocaine, Opiates 300, PCP, and THC)**

A panel of 55 naturally metabolized human urine samples was prepared. All samples in the panel had been screened for the presence or absence of AMP, COC, PCP and THC. In addition, each of the 55 samples had also been quantitated by GC/MS conducted at SAMHSA cutoffs for positive samples or at limit of quantitation for negative samples to determine the concentration of a specific drug. Five of the 55 samples were drug-free negatives and 50 of the samples were positive for one or more of the five drugs. The concentration of primary metabolite in the positive samples was between 1056 and 4622 ng/mL for AMP; 487 and 1342 ng/mL for COC; 464 and 2000 ng/mL for OPI; 32 and 109 ng/mL for PCP and 66 and 198 ng/mL for THC. The panel was used to evaluate the lot-to-lot and lab-to-lab reproducibility.

**Lot-to-Lot Reproducibility (Amphetamines, Cocaine, Opiates 300, PCP, and THC)**

Three aliquots of each of the 55 samples were prepared and each of the three sets of aliquots was coded and used to evaluate the performance of one of three lots of drug tests for the five drugs above. There was one incorrect result (a false negative on an amphetamine low positive sample) on the 825 tests for a reproducibility of >99%.

**Lab-to-Lab Reproducibility (Amphetamines, Cocaine, Opiates 300, PCP, and THC)**

Three aliquots of each of the 55 samples were prepared and each of the three sets of aliquots was tested by one of three study participants using one lot of the five drug test panel above. There was >99% agreement between the three participants. Overall, there were three incorrect results, two

incorrect results for OPI (one false negative on an opiate low positive sample and one false negative on an opiate high positive sample) and one incorrect result for PCP (one false negative a low positive sample), on the 825 tests.

**Reproducibility (Opiates 2000)**

A panel of 25 naturally metabolized human urine samples was prepared. All samples in the panel had been screened for the presence or absence of opiates. In addition, each of the positive samples had also been quantitated by GC/MS conducted at SAMHSA cutoff for positive samples to determine the concentration of morphine and codeine. The concentration of morphine and/or codeine in the positive samples was between 2000 and 6000 ng/mL. The panel was used to evaluate Opiates 2000 for lot-to-lot and lab-to-lab reproducibility. There were no incorrect results on the 75 tests (25 samples x 3 lots) for a lot-to-lot reproducibility of 100%. There were no incorrect results on the 75 tests (25 samples x 3 study participants) for a lab-to-lab reproducibility of 100%.

**Accuracy (Propoxyphene)**

One-hundred forty one (141) clinical samples were evaluated by the Roche Abuscreen OnLine Propoxyphene assay, using a 300 ng/mL cut off. Sixty (60) samples were found to be negative and eighty-one (81) samples were found to be positive by the Roche method. Three aliquots of each sample were prepared, and assayed by three operators in a masked manner. There was no significant difference in the results obtained by the three operators, therefore the results of all three operators are included in the table. Results of this comparison are as follows:

|                        | <u>OnLine Positive</u> | <u>OnLine Negative</u> |
|------------------------|------------------------|------------------------|
|                        | 238                    | 0                      |
| PPX (300 ng/mL cutoff) | 5*                     | 180                    |

\* GC/MS results are 390, 441, 499, 536 and 679 ng/mL

In addition to the 141 clinical samples, eight additional clinical samples containing only norpropoxyphene were diluted with drug-free urine in order to obtain an adequate number of samples that had concentrations of drug that were challenging to the cutoff. These eight diluted samples, and the 141 clinical samples described above were analyzed by GC/MS for propoxyphene and norpropoxyphene. The level of quantitation of the GC/MS was 30 ng/mL. Only ten of the samples contained propoxyphene, and each of these samples had norpropoxyphene levels greater than 1,647 ng/mL. As in the study above, three aliquots of the 149 samples were prepared, coded, and assayed by three operators in a masked manner. There was no significant difference in the results obtained by the three operators, therefore the results of all three operators are included in the comparison table.

| GC/MS Range (ng/mL) | None detected | 150-265             | 339-450 | >472 |
|---------------------|---------------|---------------------|---------|------|
| Number of samples   | 60            | 8 (Diluted samples) | 7       | 74   |
| Positive            | 0             | 12                  | 19      | 219  |
| Negative            | 180           | 12                  | 2       | 3    |

**Sensitivity/Precision/Distribution of Random Error (Propoxyphene)**

Performance around the specific cut-off of 300 ng/ml for norpropoxyphene was evaluated by testing standard drug solutions diluted in drug-free urine in triplicate on 5 different days by 3 operators. Drug-free urine was also tested on each day. There was no significant difference in the results of the three operators so the results were combined and are shown in the following table.

| Conc. (ng/mL) | Number Tested | Norpropoxyphene – Cut-off = 300 ng/mL |          | % Agreement |
|---------------|---------------|---------------------------------------|----------|-------------|
|               |               | Positive                              | Negative |             |
| 0             | 45            | 0                                     | 45       | 100         |
| 30            | 45            | 0                                     | 45       | 100         |
| 75            | 45            | 1                                     | 44       | 98          |
| 150           | 45            | 9                                     | 36       | 80          |
| 225           | 45            | 16                                    | 29       | 64          |
| 300           | 45            | 37                                    | 8        | 82          |
| 375           | 45            | 42                                    | 3        | 93          |
| 450           | 45            | 44                                    | 1        | 98          |
| 600           | 45            | 45                                    | 0        | 100         |

**Accuracy (Methamphetamine and MDMA)**

A panel of naturally metabolized urine samples was analyzed using the PROFILE®-III / PROFILE® -d / VERDICT®-III MAMP-MDMA and the GC/MS assay for methamphetamine and MDMA. The results obtained in the procedures are shown in the following tables.

**GC/MS Methamphetamine (limit of quantitation 50 ng/mL)**

|                                    | <u>Positive</u> | <u>Negative</u> | <u>TOTAL</u> |
|------------------------------------|-----------------|-----------------|--------------|
| MAMP (1000 ng/mL cut-off) Positive | 56              | 0               | 56           |
| Negative                           | 2               | 56              | 58           |
| TOTAL                              | 58              | 56              | 114          |

Overall agreement: >98% (112/114). Samples having discrepant results were analyzed by GC/MS. The false negative samples contained methamphetamine at 1056 ng/mL and at 1136 ng/mL.

**GC/MS MDMA (limit of quantitation 50 ng/mL)**

|                                    | <u>Positive</u> | <u>Negative</u> | <u>TOTAL</u> |
|------------------------------------|-----------------|-----------------|--------------|
| MDMA (1500 ng/mL cut-off) Positive | 19              | 1               | 20           |
| Negative                           | 4               | 57              | 61           |
| TOTAL                              | 23              | 58              | 81           |

Overall agreement: 94% (76/81). The false negative samples contained MDMA concentrations at 1641 ng/mL, 1775 ng/mL, 1800 ng/mL and 2388 ng/mL. The false positive was at 1300 ng/mL.

**Percent Agreement of MAMP-MDMA Compared to GC/MS**

|      | <u>POSITIVE</u> | <u>NEGATIVE</u> |
|------|-----------------|-----------------|
| MAMP | 97% (56/58)     | 100% (56/56)    |
| MDMA | 83% (19/23)     | 98% (57/58)     |

**Sensitivity/Precision (MAMP-MDMA)**

Performance for methamphetamine and MDMA was evaluated by testing standard drug solutions diluted in drug-free urine in duplicates of 8 drug concentrations on 5 different days by 3 operators. Drug-free urine was also tested on each day. The complete results for both drugs are shown in the tables below.

| Conc. (ng/mL) | Methamphetamine Cut-off = 1000 ng/mL |     |     |             | MDMA Cut-off= 1500 ng/mL |            |     |     |             |
|---------------|--------------------------------------|-----|-----|-------------|--------------------------|------------|-----|-----|-------------|
|               | No. Tested                           | (+) | (-) | % Agreement | Conc(ng/mL)              | No. Tested | (+) | (-) | % Agreement |
| 0             | 30                                   | 0   | 30  | 100         | 0                        | 30         | 0   | 30  | 100         |
| 100           | 30                                   | 0   | 30  | 100         | 500                      | 30         | 0   | 30  | 100         |
| 250           | 30                                   | 0   | 30  | 100         | 750                      | 30         | 0   | 30  | 100         |
| 500           | 30                                   | 26  | 4   | 87          | 1000                     | 30         | 12  | 18  | 60          |
| 750           | 30                                   | 27  | 3   | 90          | 1250                     | 30         | 23  | 7   | 77          |
| 1000          | 30                                   | 28  | 2   | 93          | 1500                     | 30         | 25  | 5   | 83          |
| 1250          | 30                                   | 29  | 1   | 97          | 2000                     | 30         | 30  | 0   | 100         |
| 1500          | 30                                   | 30  | 0   | 100         | 2500                     | 30         | 30  | 0   | 100         |
| 2000          | 30                                   | 30  | 0   | 100         | 3000                     | 30         | 30  | 0   | 100         |

**Reproducibility (MAMP-MDMA)**

A panel of 18 spiked human urine samples, comprised of drug-free and drug standard samples, was prepared. The panel was examined by 3 operators, once a day for 5 days. The concentration of methamphetamine and MDMA had been quantitated by GC/MS in each of the 18 samples. There was 100% agreement between the three operators over the 5 day period at 0 ng/mL, 1500 ng/mL (cut-off + 50%) and 2000 ng/mL (cut-off + 100%) for methamphetamine. There was also 100% agreement between the three operators over the 5 day period for 0 ng/ml, 2000 ng/mL (cut-off +33%), 2500 ng/mL (cut-off + 67%) and 3000 ng/mL (cut-off + 100%) for MDMA.

**Accuracy (Barbiturates, Benzodiazepines and Methadone)**

The accuracy was evaluated by assaying a coded panel of clinical urine samples containing varying concentrations of drugs and comparing the results to validated methods. Validated GC/MS assays measured barbiturates, benzodiazepines, and methadone levels. Results are shown in the following tables.

**ACCURACY COMPARED TO GC/MS  
(Barbiturates, Benzodiazepines, and Methadone)**

| DRUG CLASS             | Concentration Range (ng/mL) | Number of Samples | PROFILE®-III / PROFILE®-d / VERDICT®-III Results |
|------------------------|-----------------------------|-------------------|--|
| <b>Barbiturates</b>    | 201 – 27776                 | 36                | 36/36 Positive                                   |
|                        | 155, 155, 156, 158, 161     | 5                 | 5/5 Negative                                     |
| Butalbital             | 240 - 3814                  | 27                | 27/27 Positive                                   |
|                        | 109, 151, 194               | 3                 | 3/3 Positive                                     |
| Pentobarbital          | 264                         | 1                 | 1/1 Positive                                     |
| <b>Benzodiazepines</b> | 303 – 30813                 | 57                | 57/57 Positive                                   |
|                        | 234, 236, 238, 250, 283     | 5                 | 5/5 Negative                                     |
| <b>Methadone</b>       | 306 - 70560                 | 57                | 57/57 Positive                                   |
|                        | 224, 226, 227, 230, 232     | 5                 | 5/5 Negative                                     |

Additionally, the accuracy was evaluated in comparison to the Roche Diagnostics Systems, Inc, ABUSCREEN ONLINE® assays for barbiturates, benzodiazepines and methadone. A panel of clinical urine samples was analyzed and the results obtained in the procedures were compared. Results are shown in the following tables.

**ACCURACY COMPARED TO THE ROCHE ABUSCREEN ONLINE® II  
(Barbiturates, Benzodiazepines, and Methadone)**

**ABUSCREEN ONLINE® II Barbiturates Result (Secobarbital)  
(300 ng/mL cutoff)**

|                        |          | <u>Positive</u> | <u>Negative</u> | <u>Total</u> |
|------------------------|----------|-----------------|-----------------|--------------|
| BAR (200 ng/mL cutoff) | Positive | 62              | 0               | 62           |
| <b>Butalbital Test</b> | Negative | 0               | 45              | 45           |
|                        | Total    | 62              | 45              | 107          |

Overall agreement: 100% (107/107).

**ABUSCREEN ONLINE® II Benzodiazepines Result  
(300 ng/mL cutoff)**

|                         |          | <u>Positive</u> | <u>Negative</u> | <u>Total</u> |
|-------------------------|----------|-----------------|-----------------|--------------|
| BZO (300 ng/mL cutoff)  | Positive | 57              | 0               | 57           |
| <b>Nordiazepam Test</b> | Negative | 0               | 45              | 45           |
|                         | Total    | 57              | 45              | 102          |

Overall agreement: 100% (102/102).

**ABUSCREEN ONLINE® II Methadone Result  
(300 ng/mL cutoff)**

|                        |          | <u>Positive</u> | <u>Negative</u> | <u>Total</u> |
|------------------------|----------|-----------------|-----------------|--------------|
| MTD (300 ng/mL cutoff) | Positive | 55              | 0               | 55           |
| <b>Methadone Test</b>  | Negative | 0               | 45              | 45           |
|                        | Total    | 55              | 45              | 100          |

Overall agreement: 100% (100/100).



**PERCENT AGREEMENT COMPARED TO ROCHE ABUSCREEN ONLINE ASSAYS  
(Barbiturates, Benzodiazepines, and Methadone)**

|                 | <u>POSITIVE</u> | <u>NEGATIVE</u> |
|-----------------|-----------------|-----------------|
| Barbiturates    | 100% (62/62)    | 100% (45/45)    |
| Benzodiazepines | 100% (57/57)    | 100% (45/45)    |
| Methadone       | 100% (55/55)    | 100% (45/45)    |

**Sensitivity / Precision / Distribution of Random Error** (Barbiturates, Benzodiazepines, and Methadone)

Performance around the specific cutoff for each drug was evaluated by testing standard drug solutions diluted in drug-free urine in triplicate on 5 different days by 3 operators. Drug-free urine was also tested on each day. Operator-to-operator agreement was excellent, therefore, the data were combined and summarized in the following tables.

**Barbiturates (Butalbital) Cutoff = 200 ng/mL**

| <u>Conc. (ng/mL)</u> | <u>Number Tested</u> | <u>Positive</u> | <u>Negative</u> | <u>% Agreement</u> |
|----------------------|----------------------|-----------------|-----------------|--------------------|
| Negative             | 45                   | 0               | 45              | 100                |
| 50                   | 45                   | 0               | 45              | 100                |
| 100                  | 45                   | 0               | 45              | 100                |
| 150                  | 45                   | 12              | 33              | 73                 |
| 200                  | 45                   | 43              | 2               | 96                 |
| 250                  | 45                   | 45              | 0               | 100                |
| 300                  | 45                   | 45              | 0               | 100                |

**Benzodiazepines (Nordiazepam) Cutoff = 300 ng/mL**

| <u>Conc. (ng/mL)</u> | <u>Number Tested</u> | <u>Positive</u> | <u>Negative</u> | <u>% Agreement</u> |
|----------------------|----------------------|-----------------|-----------------|--------------------|
| Negative             | 45                   | 0               | 45              | 100                |
| 30                   | 45                   | 0               | 45              | 100                |
| 75                   | 45                   | 6               | 39              | 87                 |
| 150                  | 45                   | 27              | 18              | 60                 |
| 225                  | 45                   | 41              | 4               | 91                 |
| 300                  | 45                   | 42              | 3               | 93                 |
| 375                  | 45                   | 43              | 2               | 96                 |
| 450                  | 45                   | 45              | 0               | 100                |
| 600                  | 45                   | 45              | 0               | 100                |

**Methadone (Methadone) Cutoff = 300 ng/mL**

| <u>Conc. (ng/mL)</u> | <u>Number Tested</u> | <u>Positive</u> | <u>Negative</u> | <u>% Agreement</u> |
|----------------------|----------------------|-----------------|-----------------|--------------------|
| Negative             | 45                   | 0               | 45              | 100                |
| 30                   | 45                   | 3               | 42              | 93                 |
| 75                   | 45                   | 28              | 17              | 62                 |
| 150                  | 45                   | 35              | 10              | 78                 |
| 225                  | 45                   | 43              | 2               | 96                 |
| 300                  | 45                   | 45              | 0               | 100                |
| 375                  | 45                   | 45              | 0               | 100                |
| 450                  | 45                   | 43              | 2               | 96                 |
| 600                  | 45                   | 44              | 1               | 98                 |

**Accuracy (Oxycodone)**

The accuracy was evaluated by assaying a panel of blind coded clinical urine samples containing varying concentrations of drugs and comparing to GC/MS results. The samples were obtained from MEDTOX Laboratories. Samples that screened negative by the predicate device were not confirmed by GC/MS. Positive samples were confirmed by GC/MS. The GC/MS determination included Oxycodone and oxymorphone and a weighted concentration using 100% cross-reactivity for Oxycodone and a 50% cross-reactivity for oxymorphone was calculated. Clinical urine samples containing Oxycodone and oxymorphone at higher concentrations were diluted with negative urine to obtain the desired number of samples with concentrations below and above the cutoff. The testing was performed by nine MEDTOX personnel at one site.

**MEDTOX® OXYCODONE Results vs. stratified GC/MS Values**

| <b>MEDTOX® OXYCODONE Results</b> | <b>Negative by Immunoassay (Predicate Device)</b> | <b>Concentration up to 50% below the cutoff</b> | <b>Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)</b> | <b>Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)</b> | <b>High Positive (Greater than 50% above the cutoff concentration)</b> |
|----------------------------------|---|---|---|---|--|
| Positive                         | 0   | 2   | 2   | 6   | 38   |
| Negative                         | 103   | 5   | 4   | 1   | 0  |

GC/MS values used to categorize samples in this table are determined by adding together the concentration of Oxycodone plus 50% of the concentration of oxymorphone, based on the MEDTOX® OXYCODONE cross-reactivity studies.

% Agreement among positives is 98%. % Agreement among negatives is 97%

**Sensitivity/Precision (Oxycodone)**

Performance around the specific cutoff for Oxycodone was evaluated by testing standard drug solutions diluted in drug-free urine in triplicate on 6 different intervals by 3 in-house operators. Drug free urine was also tested on each interval. The results were interpreted at five minutes and are summarized below:

**MEDTOX® OXYCODONE Precision Study Results**

| <b>Concentration of sample (ng/mL)</b> | <b>Number of determinations</b> | <b>Results #Neg / #Pos</b> |
|--|---------------------------------|----------------------------|
| 0                                      | 54                              | 54 / 0                     |
| 25                                     | 54                              | 54 / 0                     |
| 50                                     | 54                              | 50 / 4                     |
| 75                                     | 54                              | 14 / 40                    |
| <b>100</b>                             | 54                              | 4 / 50                     |
| 125                                    | 54                              | 1 / 53                     |
| 150                                    | 54                              | 0 / 54                     |

### Non Crossreactive Endogenous Compounds

Fifteen compounds were dissolved in appropriate solvents at a concentration of at least 1.0 mg/mL. Each compound was further diluted to 100 µg/mL except for albumin (20 mg/mL) and bilirubin (200 µg/mL). None of these compounds showed cross-reactivity at the listed concentrations.

|                |                       |                     |
|----------------|-----------------------|---------------------|
| Acetaldehyde   | Creatinine            | Hemoglobin, Human   |
| Acetone        | Epinephrine           | Sodium Chloride     |
| Albumin, Human | β-Estradiol           | Tetrahydrocortisone |
| Bilirubin      | Estriol               | d,1-Thyroxine       |
| Cholesterol    | Glucose Std. Solution | Uric Acid           |

### Unrelated Compounds, Prescription and Over-the-Counter Medications

The following compounds were tested for reactivity. Listed compounds were dissolved in appropriate solvents and then added to drug-free urine for testing. Unless otherwise noted by a drug name abbreviation such as "AMP" or "BAR" etc., all of the listed compounds were negative in each of the tests at 100 µg/mL or the highest level tested. If a drug name is followed by an abbreviation such as "AMP" or "BAR" etc., check the "Related Compounds and Cross Reactants" listing for the drug in question under the appropriate heading (AMP, BAR, etc.) to find its level of cross-reactivity to that test.

|   |   |  |
|---|---|--|
| Acecaïnide (N-Acetylprocainamide)         | Acetaminophen                               | Acetylsalicylic Acid                         |
| Allobarbita <b>l</b> - <b>BAR</b>         | Alphenal- <b>BAR</b>                        | Alprazolam- <b>BZO</b>                       |
| Alprazolam, 1-Hydroxy- <b>BZO</b>         | p-Aminobenzoic Acid                         | 7-Aminoclonazepam                            |
| 7-Aminoflunitrazepam                      | Amino glutethimide                          | l-Aminopyrine (4-(dimethylamino) antipyrine) |
| Amitriptyline                             | Amobarbita <b>l</b> - <b>BAR</b>            | Amoxapine                                    |
| Amoxicillin                               | d-Amphetamine- <b>AMP</b>                   | l- Amphetamine- <b>AMP</b>                   |
| Ampicillin                                | Apomorphine                                 | l-Ascorbic Acid                              |
| Aspartame                                 | Atenolol                                    | Atomoxetine                                  |
| Atropine Sulfate                          | Barbita <b>l</b> - <b>BAR</b>               | Barbituric Acid                              |
| Benzilic Acid                             | Benzoic Acid                                | Benzocaine (ethyl-4-aminobenzoate)           |
| Benzoylcegonine- <b>COC</b>               | Benzphetamine                               | Benztropine                                  |
| Brompheniramine                           | Buprenorphine                               | Bupropion                                    |
| Butabarbital- <b>BAR</b>                  | Butalbital- <b>BAR</b>                      | Caffeine                                     |
| Cannabidiol                               | Cannabinol                                  | Captopril                                    |
| Carbamazepine                             | Carbamazepine- 10,11 epoxide                | Carisoprodol (Meprobamate)                   |
| Cephalexin                                | Chloral Hydrate                             | Chloramphenicol                              |
| Chlordiazepoxide                          | Chloroquine                                 | Chlorothiazide                               |
| Chlorpheniramine                          | Chlorpromazine                              | Chlorprothixene                              |
| Clobazam- <b>BZO</b>                      | Clomipramine                                | Clonazepam- <b>BZO</b>                       |
| Clonidine                                 | Clorazepate- <b>BZO</b>                     | Clozapine                                    |
| Cocaine- <b>COC</b>                       | Codeine- <b>OPI, OXY</b>                    | Cortisone                                    |
| Cotinine                                  | Cyclobenzaprine                             | Cyclopentobarbita <b>l</b> - <b>BAR</b>      |
| Deoxycorticosterone                       | Desalkylflunitrazepam- <b>BZO</b>           | Desipramine                                  |
| Desmethylchlordiazepoxide- <b>BZO</b>     | Desmethylflunitrazepam- <b>BZO</b>          | Desmethylvenlafaxine                         |
| Dexamethasone                             | Dextromethorphan                            | Diacetylmorphine- <b>OPI</b>                 |
| Diazepam- <b>BZO</b>                      | Diclofenac                                  | Diethylpropion                               |
| Diflunisal                                | Digoxin                                     | Dihydrocodeine- <b>OPI, OXY</b>              |
| Dimenhydrinate (Dramamine)                | 1,3-Dimethylbarbituric acid                 | Diphenhydramine                              |
| Diphenylhydantoin (Phenytoin)- <b>BAR</b> | Domperidone                                 | Dopamine                                     |
| Doxepin                                   | Doxylamine                                  | Ecgonine                                     |
| EDDP-(Primary metabolite of methadone)    | Efavirenz (Sustiva)                         | EMDP-(Secondary metabolite of methadone)     |
| Ephedrine- <b>MAMP</b>                    | Equilin                                     | Erythromycin                                 |
| Estrone                                   | Ethanol                                     | Ethylmorphine- <b>OPI, OXY</b>               |
| Fenfluramine- <b>MAMP</b>                 | Fenoprofen                                  | Fentanyl (Synthetic opiate)                  |
| Flunitrazepam- <b>BZO</b>                 | Fluoxetine (Prozac)                         | Flurazepam                                   |
| Furosemide                                | Fluvoxamine                                 | Gentisic Acid (2,5-Dihydroxybenzoic acid)    |
| Glutethimide                              | Guaiacol Glyceryl Ether                     | Haloperidol                                  |
| Hexobarbital                              | Hippuric acid                               | Hydralazine                                  |
| Hydrochlorothiazide                       | Hydrocodone- <b>OPI, OXY</b>                | Hydrocortisone                               |
| Hydromorphone- <b>OPI, OXY</b>            | Hydroxybupropion                            | Hydroxyhippuric Acid                         |
| l-11-Hydroxy-Δ <sup>9</sup> -THC          | p-Hydroxyphenobarbita <b>l</b> - <b>BAR</b> | 4-Hydroxyphenacyclidine- <b>PCP</b>          |
| 3-Hydroxytyramine                         | Hydroxyzine                                 | Ibuprofen                                    |
| Imipramine                                | Iproniazid                                  | (R)-Isoproterenol                            |
| Isoxsuprine- <b>COC</b>                   | Ketamine                                    | Ketoprofen                                   |
| Labetalol                                 | Levorphanol- <b>OPI</b>                     | Lidocaine                                    |
| Lithium carbonate                         | Loperamide                                  | Lorazepam- <b>BZO</b>                        |
| Lorazepam glucuronide- <b>BZO</b>         | Loxapine                                    | Lysergic Acid                                |
| Lysergic Acid Diethylamide (LSD)          | Maprotiline                                 | MDA- <b>AMP</b>                              |
| MDE (MDEA)- <b>MAMP</b>                   | MDMA  | Melanin                                      |
| Meperidine                                | Mephobarbital                               | Mepivacaine                                  |
| Mesoridazine                              | Methadone- <b>MTD</b>                       | d-Methamphetamine- <b>MAMP</b>               |
| l-Methamphetamine- <b>MAMP</b>            | Methaqualone                                | Methcathinone                                |
| Methocarbamol                             | Methoxyphenamine                            | Methylphenidate                              |
| Methylprylon                              | Metoprolol                                  | Midazolam- <b>BZO</b>                        |
| Mirtazapine                               | 6-Monoacetylmorphine- <b>OPI</b>            | Morphine- <b>OPI, OXY</b>                    |
| Morphine 3-β-D-Glucuronide- <b>OPI</b>    | Morphine 6-β-D-Glucuronide- <b>OPI</b>      | Nalidixic Acid                               |
| Naltrexone- <b>OXY</b>                    | Nalorphine- <b>OPI</b>                      | Naloxone- <b>OXY</b>                         |
| Naproxen                                  | Niacinamide                                 | Nicotine                                     |
| Nifedipine                                | Nitrazepam- <b>BZO</b>                      | Nitrofurantoin                               |
| Norclomipramine                           | Norcodeine- <b>OPI, OXY</b>                 | Nordiazepam- <b>BZO</b>                      |
| Nordoxepin                                | Norethindrone                               | Norlysergic Acid                             |
| Normeperidine                             | Norpropoxyphene- <b>PPX</b>                 | l-Norpseudoephedrine                         |
| Nortriptyline                             | Noscapine                                   | Nylidrin                                     |
| Octopamine                                | Ofloxacin                                   | Olanzapine                                   |
| Omeprazole                                | Orphenadrine                                | Oxalic Acid                                  |
| Oxaprosin                                 | Oxazepam- <b>BZO</b>                        | Oxazepam glucuronide- <b>BZO</b>             |
| Oxolinic Acid                             | Oxycodone- <b>OXY</b>                       | Oxymetazoline                                |
| Oxymorphone- <b>OXY</b>                   | Papaverine hydrochloride                    | Penicillin G                                 |
| Pentazocine                               | Pentobarbita <b>l</b> - <b>BAR</b>          | Perphenazine                                 |
| Phenacetin (Acetophenetidin)              | Phencyclidine- <b>PCP</b>                   | Phendimetrazine                              |
| Phenelzine                                | Phenethylamine- <b>MAMP</b>                 | Pheniramine                                  |
| Phenmetrazine                             | Phenobarbita <b>l</b> - <b>BAR</b>          | Phenothiazine                                |
| Phentermine- <b>AMP</b>                   | Phenytoin (Diphenylhydantoin)- <b>BAR</b>   | Phenylbutazone                               |
| Phenylephrine                             | Phenylpropanolamine                         | Piroxicam                                    |
| Prazosin                                  | Prednisolone                                | Prednisone                                   |
| Procaine                                  | Procainamide                                | Prochlorperazine                             |

Promazine  
 Propranolol  
 Pyrilamine  
 Ranitidine  
 Salicylic Acid  
 Serotonin (5-Hydroxytryptamine)  
 Sulfamethazine  
 Temazepam-**BZO**  
 $\Delta^9$ -Tetrahydrocannabinol  
 Thebaine-**OPI**  
 Thiopental  
 Tolbutamide  
 Triamterene  
 Trifluoperazine  
 Tripelennamine  
 Tyramine  
 Venlafaxine

Promethazine  
 Protriptyline  
 Quetiapine (Seroquel)  
 Riboflavin  
 Secobarbital-**BAR**  
 Sertraline (Zoloft)  
 Sulindac  
 Temazepam glucuronide-**BZO**  
 $\Delta^8$ -Tetrahydrocannabinol  
 Theophylline  
 Thioridazine  
 Tolmetin (Tolectin)  
 Triazolam-**BZO**  
 Trimethoprim  
 Tryptamine  
 Tyrosine  
 Verapamil

Propoxyphene-**PPX**  
 d-Pseudoephedrine  
 Quinidine  
 Rifampin  
 Selegiline (Deprenyl)  
 Sildenafil (Viagra)  
 Talbutal-**BAR**  
 Tetracycline  
 Tetrahydrozoline  
 Thiamine  
 Thiothixene  
 Trazodone  
 Triazolam, 1-hydroxy  
 Trimipramine  
 Tryptophan  
 Valproic Acid  
 Zomepirac

**Related Compounds and Cross Reactants**

The following metabolites and compounds were tested. Reference standards for the various metabolites and compounds were prepared in negative urine samples. None of the compounds reacted with the remaining tests in the panel. Results are expressed as the minimum concentration required to produce a positive result in the indicated assay. Compounds that reacted with the test are listed first, and related compounds that did not react with the highest concentration tested are listed second as Negative at 100,000 ng/mL (or highest level tested).

**Amphetamine- (AMP)**(d-Amphetamine) 1000 ng/mL

l-Amphetamine  
 MDA  
 Phentermine

**Result**

Positive at 100 µg/mL  
 Positive at 400 ng/mL  
 Positive at 10 µg/mL

Ephedrine  
 MDMA  
 MDE (MDEA)  
 l-Methamphetamine  
 d-Methamphetamine  
 Phenethylamine  
 Tyramine

Negative at 100 µg/mL  
 Negative at 100 µg/mL  
 Negative at 100 µg/mL  
 Negative at 100 µg/mL  
 Negative at 100 µg/mL  
 Negative at 100 µg/mL

**Barbiturate-(BAR)** (Butalbitol) 200 ng/mL

Allobarbitol  
 Alphenal  
 Amobarbital  
 Barbitol  
 Butabarbitol  
 Cyclopentobarbital  
 p-Hydroxyphenobarbital  
 Pentobarbital  
 Phenobarbital  
 Phenytoin (Diphenylhydantoin)  
 Secobarbital  
 Talbutal

**Result**

Positive at 500 ng/mL  
 Positive at 100 ng/mL  
 Positive at 2500 ng/mL  
 Positive at 2500 ng/mL  
 Positive at 750 ng/mL  
 Positive at 250 ng/mL  
 Positive at 500 ng/mL  
 Positive at 500 ng/mL  
 Positive at 800 ng/mL  
 Positive at 2500 ng/mL  
 Positive at 75 ng/mL  
 Positive at 50 ng/mL

Amino glutethimide  
 Barbituric Acid  
 1,3 Dimethylbarbituric Acid  
 Glutethimide  
 Hexobarbital  
 Mephobarbital

Negative at 100,000 ng/mL  
 Negative at 100,000 ng/mL  
 Negative at 100,000 ng/mL  
 Negative at 100,000 ng/mL  
 Negative at 100,000 ng/mL  
 Negative at 100,000 ng/mL

**Benzodiazepine-(BZO)** (Nordiazepam) 300ng/mL

Alprazolam  
 Alprazolam, 1-OH  
 Clobazam  
 Clonazepam  
 Clorazepate  
 Desalkylflurazepam  
 Desmethylchlordiazepoxide  
 Desmethylflunitrazepam  
 Diazepam  
 Flunitrazepam  
 Lorazepam  
 Lorazepam glucuronide  
 Midazolam  
 Nitrazepam  
 Oxazepam  
 Oxazepam glucuronide  
 Temazepam  
 Temazepam glucuronide  
 Triazolam

**Result**

Positive at 250 ng/mL  
 Positive at 25 µg/mL  
 Positive at 50 ng/mL  
 Positive at 250 ng/mL  
 Positive at 250 ng/mL  
 Positive at 250 ng/mL  
 Positive at 500 ng/mL  
 Positive at 75 ng/mL  
 Positive at 50 ng/mL  
 Positive at 75 ng/mL  
 Positive at 2.5 µg/mL  
 Positive at 1 µg/mL  
 Positive at 5 µg/mL  
 Positive at 50 ng/mL  
 Positive at 500 ng/mL  
 Positive at 2.5 µg/mL  
 Positive at 50 ng/mL  
 Positive at 750 ng/mL  
 Positive at 750 ng/mL

7-Aminoclonazepam  
 7-Aminoflunitrazepam  
 Chlordiazepoxide  
 Flurazepam  
 Triazolam, 1-OH

Negative at 100 µg/mL  
 Negative at 100 µg/mL  
 Negative at 100 µg/mL  
 Negative at 100 µg/mL  
 Negative at 10 µg/mL

**Cocaine-(COC)** (Benzoylcegonine) 300 ng/mL

Cocaine  
 Isoxsuprine

**Result**

Positive at 800 ng/mL  
 Positive at 6 µg/mL

Ecgonine  
 Ecgonine Methyl Ester

Negative at 100 µg/mL  
 Negative at 100 µg/mL

**Methamphetamine-(MAMP)** (d-Methamphetamine) 1000 ng/mL,

(MDMA) 1500 ng/mL

Ephedrine  
 Fenfluramine  
 MDE (MDEA)  
 l-Methamphetamine

**Result**

Positive at 2.5 µg/mL  
 Positive at 25 µg/mL  
 Positive at 5 µg/mL  
 Positive at 7.5 µg/mL

|                 |                       |
|-----------------|-----------------------|
| Phenethylamine  | Positive at 2.5 µg/mL |
| d-Amphetamine   | Negative at 100 µg/mL |
| l-Amphetamine   | Negative at 100 µg/mL |
| MDA             | Negative at 100 µg/mL |
| Phentermine     | Negative at 100 µg/mL |
| Pseudoephedrine | Negative at 100 µg/mL |
| Tyramine        | Negative at 100 µg/mL |

**Methadone-(MTD)** (Methadone) 300 ng/mL

|                             |                       |
|-----------------------------|-----------------------|
| Primary metabolite (EDDP)   | Negative at 100 µg/mL |
| Secondary metabolite (EMDP) | Negative at 100 µg/mL |

**Opiates(2000)-(OPI)** (Morphine) 2000 ng/mL

|                            |                        |
|----------------------------|------------------------|
| Codeine                    | Positive at 800 ng/mL  |
| Diacetylmorphine           | Positive at 2.0 µg/mL  |
| Dihydrocodeine             | Positive at 3 µg/mL    |
| Ethylmorphine              | Positive at 400 ng/mL  |
| Hydrocodone                | Positive at 2.0 µg/mL  |
| Hydromorphone              | Positive at 3 µg/mL    |
| Levorphanol                | Positive at 12.5 µg/mL |
| 6-Monoacetyl Morphine      | Positive at 3 µg/mL    |
| Morphine 3-β-D-Glucuronide | Positive at 3 µg/mL    |
| Morphine 6-β-D-Glucuronide | Positive at 25 µg/mL   |
| Norcodeine                 | Positive at 25 µg/mL   |
| Thebaine                   | Positive at 50 µg/mL   |

|             |                       |
|-------------|-----------------------|
| Apomorphine | Negative at 100 µg/mL |
| Nalorphine  | Negative at 100 µg/mL |
| Naloxone    | Negative at 100 µg/mL |
| Naltrexone  | Negative at 100 µg/mL |
| Oxycodone   | Negative at 100 µg/mL |
| Oxymorphone | Negative at 100 µg/mL |

**Opiates(300)-(OPI)** (Morphine) 300 ng/mL

|                            |                        |
|----------------------------|------------------------|
| Codeine                    | Positive at 100 ng/mL  |
| Diacetylmorphine           | Positive at 200 ng/mL  |
| Dihydrocodeine             | Positive at 400 ng/mL  |
| Ethylmorphine              | Positive at 200 ng/mL  |
| Hydrocodone                | Positive at 800 ng/mL  |
| Hydromorphone              | Positive at 800 ng/mL  |
| 6-Monoacetylmorphine       | Positive at 200 ng/mL  |
| Morphine 3-β-D-Glucuronide | Positive at 200 ng/mL  |
| Morphine 6-β-D-Glucuronide | Positive at 12.5 µg/mL |
| Nalorphine                 | Positive at 75 µg/mL   |
| Norcodeine                 | Positive at 12.5 µg/mL |
| Thebaine                   | Positive at 12.5 µg/mL |

|             |                       |
|-------------|-----------------------|
| Apomorphine | Negative at 100 µg/mL |
| Levorphanol | Negative at 100 µg/mL |
| Naloxone    | Negative at 100 µg/mL |
| Naltrexone  | Negative at 100 µg/mL |
| Oxycodone   | Negative at 100 µg/mL |
| Oxymorphone | Negative at 100 µg/mL |

**Oxycodone (OXY)** (Oxycodone) 100 ng/mL

|                |                          |
|----------------|--------------------------|
| Codeine        | Positive at 2,500 ng/mL  |
| Dihydrocodeine | Positive at 2,500 ng/mL  |
| Ethylmorphine  | Positive at 2,500 ng/mL  |
| Hydrocodone    | Positive at 10,000 ng/mL |
| Hydromorphone  | Positive at 10,000 ng/mL |
| Morphine       | Positive at 5,000 ng/mL  |
| Naloxone       | Positive at 10,000 ng/mL |
| Naltrexone     | Positive at 25,000 ng/mL |
| Norcodeine     | Positive at 50,000 ng/mL |
| Oxymorphone    | Positive at 200 ng/mL    |

|                            |                           |
|----------------------------|---------------------------|
| Apomorphine                | Negative at 100,000 ng/mL |
| Diacetylmorphine           | Negative at 100,000 ng/mL |
| Levorphanol                | Negative at 50,000 ng/mL  |
| 6-Monoacetylmorphine       | Negative at 100,000 ng/mL |
| Morphine 3-β-D-Glucuronide | Negative at 100,000 ng/mL |
| Morphine 6-β-D-Glucuronide | Negative at 10,000 ng/mL  |
| Nalorphine                 | Negative at 100,000 ng/mL |
| Thebaine                   | Negative at 100,000 ng/mL |

**Propoxyphene-(PPX)** (Norpropoxyphene) 300 ng/mL

|              |                      |
|--------------|----------------------|
| Propoxyphene | Positive at 50 ng/mL |
|--------------|----------------------|

**Phencyclidine-(PCP)** (Phencyclidine) 25 ng/mL

|                        |                     |
|------------------------|---------------------|
| 4-Hydroxyphencyclidine | Positive at 5 µg/mL |
|------------------------|---------------------|

**Cannabinoids-(THC)** (11-nor-9-carboxy-Δ<sup>9</sup>-THC) 50 ng/mL

|                                      |                       |
|--------------------------------------|-----------------------|
| Cannabidiol                          | Negative at 100 µg/mL |
| Cannabinol                           | Negative at 100 µg/mL |
| l-11 Hydroxy-Δ <sup>9</sup> -THC     | Negative at 50 µg/mL  |
| Δ <sup>8</sup> -Tetrahydrocannabinol | Negative at 100 µg/mL |
| Δ <sup>9</sup> -Tetrahydrocannabinol | Negative at 100 µg/mL |

#### Interference-Oxycodone Only

##### pH and Specific Gravity:

The MEDTOX<sup>®</sup> OXYCODONE test was assayed with six negative clinical samples with pH values of 4.0, 5.0, 6.0, 7.0, 8.0 and 9.0 ± 0.1. Each sample was assayed in triplicate. The pH samples were fortified with Oxycodone to the concentrations of 25 ng/mL and 150 ng/mL. All the pH levels gave negative results when fortified to 25 ng/mL, and all pH levels gave positive results when fortified to 150 ng/mL.

The MEDTOX<sup>®</sup> OXYCODONE test was assayed with eight samples with specific gravity values of 1.003, 1.005, 1.010, 1.015, 1.020, 1.025, 1.030 and 1.035 ± 0.001. Each sample was assayed in triplicate. The specific gravity samples were fortified with Oxycodone to the concentrations of 25 ng/mL and 150 ng/mL. All the specific gravity levels gave negative results when fortified to 25 ng/mL, and all specific gravity levels gave positive results when fortified to 150 ng/mL.

##### Common Drugs:

Following the study of M.L. Smith, et. al.<sup>6</sup> drug free urine samples were spiked with Oxycodone to the concentrations of 25 ng/mL and 150 ng/mL. 100 µg/mL of the common drugs were then added to the preparation and assayed by the MEDTOX<sup>®</sup> OXYCODONE test. Samples were evaluated in triplicate by in-house operators. None of the common drugs listed in the following table affected the expected results.

|                         |                   |                   |
|-------------------------|-------------------|-------------------|
| Acetylsalicylic Acid    | Chlorpheniramine  | Ibuprofen         |
| Acetaminophen           | Cocaine           | Morphine-OPI      |
| Brompheniramine maleate | Dextromethorphan  | Phenobarbital     |
| Caffeine                | Diphenylhydantoin | d-Pseudoephedrine |
| Carbamazepine           | Doxylamine        | Salicylic Acid    |

#### Interference Methamphetamine Only

##### Common Drugs:

Following the study of M.L. Smith, et. al.<sup>6</sup> the following drugs were tested to determine the degree of interference they may have on the test. Commercial negative urine was spiked with 100 µg/mL of each of these drugs and with 600 ng/mL of methamphetamine. Each spiked sample was tested in triplicate on the test. None of these drugs affected the expected negative or positive results with the 600 ng/mL fortified samples. The drugs are listed below.

|                         |                   |                   |
|-------------------------|-------------------|-------------------|
| Acetylsalicylic Acid    | Chlorpheniramine  | Ibuprofen         |
| Acetaminophen           | Cocaine           | Morphine-OPI      |
| Brompheniramine maleate | Dextromethorphan  | Phenobarbital     |
| Caffeine                | Diphenylhydantoin | d-Pseudoephedrine |
| Carbamazepine           | Doxylamine        | Salicylic Acid    |

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#### **15. LIMITED EXPRESS WARRANTIES**

The manufacturer makes no express warranty other than the diagnostic test kit will measure certain drugs and/or drug metabolites when used in accordance with the manufacturer's printed instructions. The use of the kit for any other purpose is outside the intended use of this product. The manufacturer gives no express warranty as to what the legal or clinical significance is of the levels of drug(s)/drug metabolites detected by the PROFILE<sup>®</sup>-III / PROFILE<sup>®</sup>-d / VERDICT<sup>®</sup>-III Drugs of Abuse Test. The manufacturer disclaims any and all implied warranties of merchantability, fitness for use or implied utility for any other purposes. Any and all damages for failure of the kit to perform to its instructions are limited to the replacement value of the kit.

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U.S. Patent Nos. 6,566,051, 6,376,251, 6,653,139, 7,458,942

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